

**REMARKS**

Applicants have studied the Office Action mailed March 10, 2006 and have made amendments to the specification. It is respectfully submitted that the application, as amended, is in condition for allowance. Reconsideration and allowance of the pending claims in view of the above amendments and following remarks is respectfully requested.

**Title:**

The Examiner stated that the title of the invention is not descriptive, and a new title is required that is clearly indicative of the invention to which the claims are directed.

The title is hereby amended, as indicated above, to be more indicative of the invention to which the claims are directed.

**Abstract:**

The Examiner stated that the abstract of the invention is not descriptive, and a new abstract is required that is clearly indicative of the invention to which the claims are directed.

The abstract is hereby amended, as indicated above, to be more indicative of the invention to which the claims are directed.

**Rejection of claims 3, 24-30, and 35-36 under 35 USC §102(e):**

The Examiner rejected claims 3, 24-30, and 35-36 under 35 USC §102(e) as being anticipated by U.S. Patent No. 6,511,834.

In making this rejection, the Examiner states that the '834 patent teaches polyclonal and monoclonal antibodies to full-length human dehydrogenase proteins or to antigenic peptide fragments. The human dehydrogenase of SEQ ID NO:8 is 85.9% homologous with SEQ ID NO:2 of the instant application. The Examiner asserts that an antibody to human dehydrogenase of SEQ ID NO:8 would cross-react with SEQ ID NO:2 of the instant application. The Examiner states that, in addition, the '834 patent teaches that antibodies can be coupled to a detectable substance, such as horseradish peroxidase, and also teaches that antibody fragments can be made.

In response, Applicants respectfully assert that the '834 patent does not anticipate claims 3, 24-30, and 35-36.

The Examiner asserts that the antibody taught by the '834 patent will inherently cross-react and thus bind to the same polypeptides (i.e., polypeptides comprising or consisting of SEQ ID NO:2) as the instantly claimed antibodies, thereby anticipating the instant claims. However, inherency may only be relied upon where the consequences of following the reference disclosure always necessarily results in the claimed invention. If there is not a reasonable certainty that the claimed subject matter will necessarily result, the rejection is not proper.

Specifically, in order for the antibody of the '834 patent to inherently anticipate the instant claims, the antibody of the '834 patent must necessarily selectively bind to the polypeptides recited in the instant claims (i.e., polypeptides comprising or consisting of SEQ ID NO:2). It is not sufficient that the antibody of the '834 patent may possibly or probably bind to the polypeptides recited in the instant claims.

However, this "possibly or probably" standard appears to be the standard that the Patent Office is relying on for the rejection of claims 3, 24-30, and 35-36 under 35 USC §102(e). The Examiner has cited a reference that teaches an antibody that may possibly or probably selectively bind to polypeptides of SEQ ID NO:2 because the reference antibodies are to a protein that is 85.9% homologous to SEQ ID NO:2. However, this does not mean that the reference antibodies must necessarily selectively bind to polypeptides of SEQ ID NO:2.

It is Applicant's position that the antibody of the '834 patent does not necessarily selectively bind to polypeptides of SEQ ID NO:2 because different epitopes must necessarily exist in the protein of SEQ ID NO:2 compared with SEQ ID NO:8 of the '834 patent because of the significant differences that exist in their amino acid sequences. For example, the amino acid sequence of instant SEQ ID NO:2 differs from SEQ ID NO:8 of the '834 patent by at least 14.1%. Therefore, due at least to this substantial difference in the protein structures, the antibody taught by the '834 patent does not necessarily cross-react with the same proteins (i.e., proteins comprising or consisting of SEQ ID NO:2) as the antibodies of claims 3, 24-30, and 35-36.

Accordingly, Applicants respectfully request that the rejection of claims 3, 24-30, and 35-36 under 35 USC §102(e) be reconsidered and withdrawn.

#### **Rejection of claims 31-34 under 35 USC §103(a):**

The Examiner rejected claims 31-34 under 35 USC §103(a) as being unpatentable over U.S. Patent No. 6,511,834 in view of Harlow et al.

In making these rejections, the Examiner states that Harlow et al. teach that antibodies in compositions comprising phosphate saline (PBS) can be used for immunochemical techniques. The Examiner asserts that, therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the antibody, as taught by the '834 patent, with a pharmaceutically acceptable carrier, as taught by Harlow et al., and one of ordinary skill in the art would have been motivated to do so and would have had a reasonable expectation of success.

However, in light of the discussion above in regards to the anticipation rejection under 35 USC §102(e) in view of U.S. Patent No. 6,511,834, it is clear that the '834 patent, even in combination with Harlow et al., neither anticipates nor makes obvious any of claims 31-34 due at least to the significantly different epitopes that necessarily exist because of the extensive amino acid sequence differences in SEQ ID NO:8 of the '834 patent compared with SEQ ID NO:2 of the instant application (for example, SEQ ID NO:2 differs from SEQ ID NO:8 of the '834 patent by at least 14.1%). This obviates the teachings of Harlow et al. with respect to U.S. Patent No. 6,511,83 as it applies to claims 31-34 under 35 USC §103(a).

Accordingly, Applicants respectfully request that the rejection of claims 31-34 under 35 USC §103(a) be reconsidered and withdrawn.

### Conclusions

Claims 3 and 24-36 remain pending.

In view of the above amendments and remarks, Applicants respectfully submit that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the objections and rejections. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned agent at (240) 453-3812 should the Examiner believe a telephone interview would advance prosecution of the application.

Respectfully submitted,  
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